

# EXHIBIT C

EXPERT REPORT

**Analysis of Distributor and Manufacturer  
Regulatory Compliance to Maintain  
Effective Controls for the Prevention of  
Diversion of Controlled Substances**

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Huddle Guide appears to be the first written instructions addressing the SOM issue that CVS ever provided to Pickers and Packers.

Other policies and procedures that CVS produced appear to be different versions of documents discussed above, or, in some cases, documents that relate to the new SOM system CVS gradually rolled out in 2014 (the first distribution center going live on March 2, 2014). Due to the limited amount of time that CVS distributed opioids after the introduction of the new SOM system, I have not been asked to opine on this system. I am, however, aware of some of the issues that were raised internally regarding the effectiveness of the new system.<sup>423</sup>

### **3. Enforcement Actions**

In August, 2013 the DEA initiated a regulatory investigation at the CVS Distribution Center in Indiana.<sup>424</sup> After the investigation and after the DEA had outlined some concerns with what it found at CVS, Mark Nicastro, the CVS Indiana Director of Operations, sent correspondence to the DEA. CVS cited the robust “due diligence processes in our pharmacy operations group, which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores” as the “primary contributor to the limited number of suspicious orders identified through our distributor SOM process.”<sup>425</sup> The sufficiency of the pharmacy level due diligence component of the CVS SOM program is belied by numerous DEA actions against CVS for the significant due diligence failures in its pharmacy operation, including the following:

- a. On October 13, 2010, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA to resolve the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada and a CVS/pharmacy distribution center in Southern California. The CVS Distribution Center in La Habra, California, was in a position to monitor and report excessive PSE sales to the DEA, but failed to do so, in violation of 21 U.S.C. Sec. 830(b) and 21 C.F.R. Sec. 1310.05(a)(1). CVS paid a penalty of \$75,000,000 and forfeited \$2.6 million in profits for a total payment of \$77.6 million.<sup>426</sup>
- b. On March 28, 2013, CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy L.L.C. entered into a Settlement Agreement with the United States and the DEA to resolve claims that CVS violated the CSA by : (1) filling prescriptions for certain prescribers whose DEA

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<sup>423</sup> Schiavo Depo., 374:23-385:22.

<sup>424</sup> CVS-MDLT1-00008014-00008015.

<sup>425</sup> Nicastro Depo., 203-206; Ex. 42.

<sup>426</sup> See Non-Prosecution Agreement found at <http://lib.law.virginia.edu/Garrett/corporate-prosecution-registry/agreements/cvs.pdf> . See also CVS press release announcing Settlement found at <https://cvshealth.com/newsroom/press-releases/cvsparmacy-announces-agreements-us-drug-enforcement-administration-and-us-attorneys-offices>.